

EXHIBIT 10

A Comparison of the Physiological Effects of Caffeine and Dimethylamylamine (DMAA)

The compound, 1,3-dimethylamylamine (DMAA) is a central nervous system stimulant added to some dietary supplements. It shares similar pharmacological effects in humans with caffeine (1,3,7-trimethylxanthine), a central nervous system stimulant consumed worldwide in the diet.

Both DMAA and caffeine are amine, or alkaloid-type, compounds occurring naturally in plants. Caffeine is found in coffee, tea, cacao beans (source for chocolate and cocoa) guarana, mate, bissu nuts and kola nuts, though the compound has been identified in more than 60 plant species (Frary et al. 2005, Barone et al. 1996). DMAA has been found in parts-per-billion to parts-per-million concentration levels in both geranium (*Pelargonium graveolens*) plant tissue (stems and leaves) and distilled plant oil (Li et al. 2012, Ping et al. 1992, USPlabs 2012).

Caffeine is consumed by more than 80% of the world's population each day and 82-87% of the U.S. population (Frary et al. 2005, Heckman et al. 2012). Published values of average daily caffeine intake from beverage consumption in the U.S. range from 106-170 mg/day for adults and 120 mg/day for all ages (Knight et al. 2004). Total average daily caffeine intake in the U.S. from food and beverages is 227-300 mg/day for adults and 193 mg/day for all consumers (Frary et al. 2005, Knight et al. 2004). Caffeine consumption by U.S. adults, expressed on a per body weight basis, was reported to be approximately 4 mg/kg/day (Knight et al. 2004), which can be attained by consuming 2-4 cups of coffee or 2-6 cups of brewed tea. Outside of the U.S., daily average caffeine intake of 400 mg/day (or 6 mg/kg/day for a 70 kg adult) has been reported (Biaggioni and Davis 2002), with average intake in Denmark reported to be 7 mg/kg/day (Barone et al. 1996).

Nawrot et al. (2003), in their comprehensive review of the literature, estimated a safe level of daily caffeine consumption of 400 mg/day, which was not associated with adverse health effects for healthy adults. However, doses as high as 750 mg/day have also been shown to be well tolerated in normal subjects (Biaggioni and Davis 2002), while patients with cardiovascular disease exhibited favorable tolerance for doses of up to a 250 mg dose (Hirsch et al. 1989).

The similarities between caffeine and DMAA for physiological changes in hemodynamic effects were reported in adults in a randomized, double-blinded, crossover clinical study (Bloomer et al. 2011). Ten healthy men and women were given 250 mg caffeine or 50 mg DMAA while at a rest. Caffeine ingestion resulted in an average maximum increase in systolic (SBP) and diastolic blood pressure (DBP) of 6 mm Hg and a decrease in heart rate of 5 beats per minute (bpm) over a 120 minute period after administration. A 50 mg dose DMAA resulted in an average maximum increase in SBP and DBP of 7 and 8 mm Hg, respectively, while heart rate decreased by 4 bpm. The changes in blood pressure and heart rate following doses of 250 mg caffeine or 50 mg DMAA were not statistically different.

In this same study, Bloomer et al. (2011a) reported that doses of 75 mg DMAA (which is 25% to 275% greater than in a labeled single serving of the USPlabs products OxyElite Pro™ or Jack3d™) resulted in average maximum increases in SBP and DBP of 16 and 9 mm Hg, respectively, along with a decrease in heart rate of 3 bpm. The increases in SBP and DBP from 75 mg DMAA doses are not significantly different from those reported in other clinical studies involving similar subject populations. Robertson et al. (1978), in a double-blind crossover clinical study, gave 250 mg caffeine to nine young, healthy men and women at rest. The average maximum increase in SBP and DBP was 14 mm Hg and 10 mm Hg, respectively, while heart rate decreased initially and then increased slightly. Nurminen et al. (1999) reported that a 250 mg caffeine dose in adults produced an average maximum increase in SBP and DBP of 12 mm Hg and 13 mm Hg, respectively. In a single-dose study evaluating the hemodynamic effects of Jack3d™, Farney et al. (2012) reported that a double serving of the product, providing 40 mg of DMAA and 250 mg of caffeine, resulted in an average maximum increase in SBP and DBP of 13 and 8 mm Hg. DMAA and caffeine also share similar hemodynamic effect profiles over time; peak magnitude of effects appear within 30-60 minutes post-administration, followed by a gradual decline to baseline (Hirsch et al. 1989, Robertson et al. 1978, Farney et al. 2012, Marsh et al. 1951, Mort and Kruse 2008). Thus, the effects of DMAA consumed in labeled servings of Jack3d™ and OxyElite Pro™ upon blood pressure are quite similar to those seen with a 250 mg dose of caffeine, the amount found in 2-3 cups of coffee or 2-6 cups of brewed tea.

For caffeine, the transient reduction in heart rate concomitant with the increase in blood pressure is thought to arise from the baroreceptor reflex, in which an increase in blood pressure results in

a decrease in heart rate (Lane and Manus 1989). This homeostatic mechanism aids in maintaining a steady total cardiac workload. It is only when the baroreceptor reflex is overcome that this does not occur. The initiation of the baroreceptor reflex was indicated in clinical studies of resting adults who consumed DMAA (Bloomer et al. 2011a, Farney et al. 2012, Whitehead et al. 2012, Marsh et al. 1951). Additionally, strenuously exercising adults who consumed DMAA or placebo exhibited no difference in heart rate, indicating that labeled DMAA use does not increase cardiac workload (Bloomer et al. 2011b). Tachyphylaxis, the partial tolerance to changes in blood pressure after an initial administration, appears to occur for both caffeine and DMAA (25, 26).

Both caffeine and DMAA have both exhibited very good tolerance by adults. Caffeine consumption levels substantially higher (400-500 mg/day) than those typically (275-300 mg/day) consumed are considered well tolerated (Kivity et al. 1990). Similarly, DMAA was shown to be well tolerated alone or in finished dietary supplement formulations (Bloomer et al. 2011a, Farney et al. 2012, Bloomer 2012, Whitehead et al. 2012, Bloomer et al. 2011b, McCarthy et al 2012a, McCarthy et al. 2012b) with no adverse health impacts reported. Furthermore, a dose 3 mg/kg DMAA dose (3.5 to 10.5 times greater than DMAA in labeled servings of OxyElite Pro or Jack3d for a 70 kg adult) has also been explored in a small group of individuals and also was shown to be well tolerated, with no serious adverse events. Recent clinical trials of DMAA and caffeine consumed in combination provide hemodynamic data for subjects that ingested both compounds just prior to exercise (Farney et al. 2012, Whitehead et al. 2012, Bloomer et al. 2011b), post exercise (Bloomer et al. 2011b), and over the course of time in which regular exercise was performed (Farney et al. 2012, Whitehead et al. 2012, McCarthy et al. 2012b). The available data for DMAA and caffeine do not indicate that consumption of both compounds in the dietary supplements OxyElite Pro™ or Jack3d™ would increase the susceptibility of adults to adverse cardiovascular events while exercising.

References

Barone JJ and Roberts HR. Caffeine consumption. Food Chem Toxicol. 1996 Jan;34(1):119-129.

Biaggioni I and Davis SN. Caffeine: a cause of insulin resistance? Diabetes Care. 2002 Feb;25(2):399-400.

Bloomer RJ, Harvey IC, Farney TM et al. Effects of 1,3-dimethylamylamine and caffeine alone or in combination on heart rate and blood pressure in healthy men and women. Phys Sportsmed. 2011 Sep;39(3):111-120.

Bloomer RJ, McCarthy CG, Farney TM et al. Effect of caffeine and 1,3-dimethylamylamine on exercise performance and blood markers of lipolysis and oxidative stress in trained men and women. J Caffeine Res. 2011 Sep;1(3):169-177.

Bloomer RJ. PowerPoint presentation. 2012. Unpublished data.

Charlier R. On the pharmacology of 2-amino-4-methylhexane. Arch In Pharmacodyn Ther. 1950 Sep1;83(4):573-584 (Translation).

Farney TM, McCarthy CG, Canale RE, et al. Hemodynamic and hematologic profile of healthy adults ingesting dietary supplements containing 1,3-dimethylamylamine and caffeine. Nutrition and Metabolic Insights 2012;5 1-12.

Frary CD, Johnson RK, Wang MQ. Food sources and intakes of caffeine in the diets of persons in the United States. J Am Diet Assoc. 2005 Jan;105(1):110-113.

Heckman MA, Weil J, Gonzalez de Mejia E. Caffeine (1,3,7-trimethylxanthine) in foods: a comprehensive review on consumption, functionality, safety, and regulatory matters. J Food Sci. 2010 Apr;75(3):R77-87.

Hirsch AT, Gervino EV, Nakao S, et al. The effect of caffeine on exercise tolerance and left ventricular function in patients with coronary artery disease. Ann Intern Med. 1989 Apr 15;110(8):593-598.

Kivity S, Ben Aharon Y, Man A, et al. The effect of caffeine on exercise-induced bronchoconstriction. *Chest*. 1990 May;97(5):1083-1085.

Knight CA, Knight I, Mitchell DC, et al. Beverage caffeine intake in US consumers and subpopulations of interest: estimates from the Share of Intake Panel survey. *Food Chem Toxicol*. 2004 Dec;42(12):1923-1930.

Lane JD & Manus DC. Persistent cardiovascular effects with repeated caffeine administration. *Psychosom Med*. 1989 Jul-Aug;51(4):373-380.

Li J, Chen M, Li ZC. Identification and quantification of dimethylamylamine in geranium by liquid chromatography tandem mass spectrometry. 2012 (Submitted for publication).

Marsh DF, Howard A, Herring DA. The comparative pharmacology of the isomeric nitrogen methyl substituted heptylamines. *J Pharmacol Exp Ther*. 1951 Nov;103(3):325-329.

McCarthy CG, Farney TM, Canale RE et al. A Finished Dietary Supplement Stimulates Lipolysis and Metabolic Rate in Young Men and Women. *Nutrition and Metabolic Insights* 2012;5 23-31.

McCarthy CG, Canale RE, Alleman Jr. RJ et al. Biochemical and Anthropometric Effects of a Weight Loss Dietary Supplement in Healthy Men and Women. *Nutrition and Metabolic Insights* 2012;5 13-22.

Mort JR & Kruse HR. Timing of blood pressure measurement related to caffeine consumption. *Ann Pharmacother*. 2008 Jan;42(2):105-110.

Nawrot P, Jordan S, Eastwood J, et al. Effects of caffeine on human health. *Food Addit Contam*. 2003 Jan;20(1):1-30.

Nurminen ML, Nittynen L, Korpela R, et al. Coffee, caffeine and blood pressure: a critical review. *Eur J Clin Nutr*. 1999 Nov;53(11):831-839.

Ping Z, Jun Q, Qing L. A study on the chemical constituents of geranium oil. J Guizhou Inst Technol. 1992 25:82-85.

Robertson D, Frolich JC, Carr RK, et al. Effects of caffeine on plasma renin activity, catecholamines and blood pressure. N Engl J Med. 1978 Jan 26;298(4):181-186.

USPlabs LLC. Data on file. Analysis of 1,3- and 1,4-dimethylpentylamine by LC-MS/MS.

Whitehead PN, Schilling BK, Farney TM, et al. Impact of a dietary supplement containing 1,3-dimethylamylamine on blood pressure and bloodborne markers of health: a 10-week intervention study. Nutrition and Metabolic Insights 2012;5 33-39.